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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/668,792	09/23/2003	Bernard E. Cabana	4354-110	4322

23448 7590 10/13/2010

INTELLECTUAL PROPERTY / TECHNOLOGY LAW
PO BOX 14329
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EXAMINER	
SPIVACK, PHYLLIS G	

ART UNIT	PAPER NUMBER
1614	

MAIL DATE	DELIVERY MODE
10/13/2010	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/668,792	CABANA ET AL.	
	Examiner	Art Unit	
	Phyllis G. Spivack	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *29 July 2010*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-5,44-49,52-57 and 59-61* is/are pending in the application.

4a) Of the above claim(s) *44-48* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-5, 49, 52-57, 59-61* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Applicants' Amendment filed July 29, 2010 is acknowledged. Claim 58 is canceled. Claims 44-48 remain withdrawn from consideration by the Examiner, 37 CFR 1.142(b), as drawn to non-elected inventions. All of the claims that are presently under consideration are drawn to compositions.

An amended Abstract is noted.

Those objections and rejections set forth in the last Office Action that are not herein reiterated are withdrawn. The following rejection constitutes the only rejection presently applied to the instant claims.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-5, 49, 52-57 and 59-61 are rejected under 35 U.S.C. 103(a) as being unpatentable over Eisenstein, B., US 2004/0106590, in view of Remington's Pharmaceutical Sciences.

Eisenstein teaches single dose oral administration of compositions, that may be in the form of tablets or capsules, comprising rifalazil in an amount 0.01 mg to 1000 mg. Oral preparations in the amount of 5 mg are disclosed. See paragraphs 26-30 on page 3. Dosing may be daily, as required by the instructions of instant claims 53-57, such as

for 1-14 days or 1 to 31 days. See paragraph 8 on page 1. As required by instant claim 49, an initial dose may be administered and then subsequently followed by a maintenance dose. See paragraph 8 on page 1 and claim 9 on page 6. Remington further provides motivation to prepare a pharmaceutical formulation for oral administration comprising an antibiotic having first and second dosages with a higher amount of active antibiotic in the first dosage unit, as required by instant claim 49. Loading doses are used in many drug regimens when an urgent need exists to achieve a drug steady state.

All pharmaceutical preparations that are dispensed to a patient are packaged in pharmaceutical containers along with instructions for administration. Eisenstein teaches the inclusion of instructional material on page 2, paragraph 13. The mere placement of instructions within a formulation comprising rifalazil would have been within the general knowledge of one of ordinary skill in the art at the time of the invention. Such a person would have been motivated to do so to promote proper use of the formulation to patients in need thereof and to facilitate patient compliance with a prescribed regimen. Providing such a formulation in a portable container, or in unit dose packaging, that can be transported to allow for convenient dosing, is conventional.

Claims 53-57 and 59-61 are drawn to compositions having instructions for administration. It has been held that Applicants are not entitled to patent a known product by simply attaching a set of instructions to that product. See *In re Ngai*, 367 F.3d 1336, 70 U.S.P.Q.2d 1862 (Fed. Cir. 2004).

The determination of an optimal dosing regimen is well within the purview of those skilled in the art through no more than routine experimentation. See *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233,235 (CCPA 1955) and MPEP 2144.05(II).

Intended use confers no patentable weight to composition claims. A pharmaceutical composition must be both new and unobvious to one skilled in the art. *In re Hack*, 114 USPQ 161 (CCPA 1957). Claim 49 recites "providing instructions for the use of said formulation," and the use is as an antibiotic. However, the instant composition claims do not have any structural differences from the prior art compositions. Therefore, there is no patentable distinction between the claimed invention and the prior art compositions. The pharmaceutical compositions that are disclosed by Eisenstein are capable of performing the same antimicrobial use as those instantly claimed.

Remington is properly applied as a secondary reference to show a dosing regimen wherein a higher amount of active antibiotic, i.e., in a loading dose regimen, is dispensed in a first dosage to achieve a therapeutic drug concentration quickly. Such loading doses, as taught by Remington, reflect conventional practice in that the first dose has a higher amount of drug and is followed by a second lower dose, considered to be a maintenance dose.

In view of the combined teachings of Eisenstein and Remington, one skilled in the art of formulation chemistry would have been motivated to prepare unit dose packaging of the drug rifalazil in an amount between 0.1-5 mg/unit for oral

administration, optionally with instructions. A unit dosage is a finite, discrete drug entity having a specific amount of that drug. Such packaging is entirely conventional.

According to Remington, packaging of pharmaceutical agents as unit doses, along with instructions thereto, comprising a loading dose, followed by a second, lower dosage unit, is conventional therapeutic practice.

Applicants' argument is drawn to an assertion that the Eisenstein reference is not available as prior art under 35 U.S.C. 102 (a) or (b). Applicants argue Eisenstein was subject to an obligation of assignment to the same entity as the instant application and so is not available as prior art under 103(c).

Eisenstein is available as prior art under 35 U.S.C. 102(e). There is no indication of common ownership at the time of filing. The rejection might be overcome by a showing under 37 CFR 1.131.

No claim is allowed.

Applicants' Amendment necessitated the new ground of rejection of claims 59 and 60 that is presented in this Office Action. Claim 61 was inadvertently omitted from the rejection of record under 35 U.S.C. 103. Claim 61 is properly included in the rejection as evidenced by the inclusion of claims 5 and 52. **THIS ACTION IS MADE FINAL**. Applicants are reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this Final Action is set to expire THREE MONTHS from the mailing date of this Action. In the event a first reply is filed within

TWO MONTHS of the mailing date of this Final Action and the Advisory Action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the Advisory Action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the Advisory Action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this Final Action.

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Phyllis G. Spivack whose telephone number is 571-272-0585. The Examiner can normally be reached from 10:30 to 7 PM.

If attempts to reach the Examiner by telephone are unsuccessful after one business day, the Examiner's supervisor, Ardin Marschel, can be reached 571-272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

March 27, 2010

/Phyllis G. Spivack/
Primary Examiner, Art Unit 1614